



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,604	03/31/2004	Thomas Palmieri	2006P26237 US	4357

28524 7590 06/04/2008
SIEMENS CORPORATION
INTELLECTUAL PROPERTY DEPARTMENT
170 WOOD AVENUE SOUTH
ISELIN, NJ 08830

EXAMINER

WRIGHT, PATRICIA KATHRYN

ART UNIT	PAPER NUMBER
----------	--------------

1797

MAIL DATE	DELIVERY MODE
-----------	---------------

06/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/813,604	Applicant(s) PALMIERI ET AL.	
	Examiner P. Kathryn Wright	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-47 is/are pending in the application.
- 4a) Of the above claim(s) 39-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-38 is/are rejected.
- 7) ☒ Claim(s) 27-38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. This action is in response to papers filed March 03, 2008 in which claims 1-26 were canceled and claims 27-47 were added. The amendments have been thoroughly reviewed and entered.

Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. Any objection/rejection not repeated herein has been withdrawn by the Office. New grounds for rejection, necessitated by the amendments, are discussed.

Election/Restrictions

2. Newly submitted claims 39-47 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

- I. Claims 27-38, are drawn to a multi-path access system, classified in class 422, subclass 63.
- II. Claims 39-46, are drawn to a multi-path access system, classified in class 422, subclass 65.
- III. Claim 47, is drawn to a method for controllably moving sample in an automated analyzer, classified in class 436, subclass 50.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions III and [I,II] are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be

practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus of Groups I and II, as claimed can be used to practice another and materially different process which does not require the step of optimizing the path for each sample such that samples having identical resource requirements travel an equal distance around the first continuous loop as required in Group III.

4. Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require a transfer shuttle, positioned to slide in a direction perpendicular to a portion of the transporter device, for moving vessels to and from the vessels holders. The subcombination has separate utility such as means mix the sample in vessels.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or

includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

5. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

6. Since applicant has received an action on the merits for the originally presented invention, which corresponds to most closely to Group I (new claims 27-38), this invention has been **constructively elected by original presentation for prosecution**

on the merits. Accordingly, claim 39-47 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Drawings

7. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “means for delivering” in claim 32 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

8. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: “means for holding” and “means for moving” in the transport device of claim 27; “means moving” in the transfer station of claim 27, “vessel holding means” in claim 27; “means for holding” and “means for moving”, the transfer station “means for moving ” in claim 31, “means for delivering” in claim 32; and “means for moving” the vessel holding means in claim 38.

The rules of the PTO require that application claims must “conform to the invention as set forth in the remainder of the specification and the **terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.**” 37 CFR 1.75(d)(1).

Claim Objections

9. Claims 27-38 are objected to because of the following informalities: Claim 27 recites the limitation “a transport device comprising means for holding” and a “means for moving” in item (a), and a “transfer station comprising a means for moving” in item (b). Claim 31 recites “a second transport device comprising a means for holding, and means for moving” and “a transfer station comprises a means for moving”. For the sake of clarity in claim 31, the Examiner recommends Applicant change “means for holding”,

and “means for moving” to --second means for holding-- and --second means for moving--, respectively.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. New claim 32 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In addition, claim 32 recites a delivery station comprising a “means for delivering” one or more vessels to the transport device. While the original specification does broadly disclose the delivery station 201 at pages 3, 8, 12, 13 and 14, the Examiner can not locate support for the delivery means having a “means for delivering” in the specification as originally filed. Nor has Applicant disclosed in the Reply where this new limitation finds support. Thus, the claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. New claims 27-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 recites the limitation "a transport device comprising **means for holding**" and a **means for moving**" in item (a) and a "transfer station comprising a **means for moving**" in item (b).

Claim 31 recites "a second transport device comprising a **means for holding**, and **means for moving**" and "a transfer station comprises a **means for moving**".

Claim 32 recites "means for delivering".

Claim 38 recites "means for moving".

The Examiner has interpreted these limitations as a **means-plus-function limitation covered by 35 USC 112, sixth paragraph**. This interpretation is proper since the claim limitations recite "means for" language, and the "means for" is not modified by sufficient structure for achieving the specified function. A means-plus-function limitation recites a function to be performed rather than definite structure or materials for performing that function. For claims falling under 35 USC 112, sixth paragraph, Examiners are required to construe claims as covering the corresponding structure, material, or acts described in the specification and equivalents thereof, see *In re Donaldson Co.*, 29 USPQ2d 1845 (Fed. Cir. 1994). However, the specification does not set forth the corresponding structure with respect all of the above mentioned mean-

plus-function limitations. Thus, it is unclear and indefinite what structure Applicant is intending to encompass with the "means for holding" , "means for moving" in claim 27, "means for holding", means for moving" in claim 31, "means for delivering" in claim 32, and "means for moving" in claim 38.

Since Applicant fails to set forth an adequate disclosure, Applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112. Clarification is required.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 27-38, as best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Babson et al. (US Patent no. 5,885,529), hereinafter "Babson".

Babson teaches a multipath access system for use in an automated immunoassay analyzer. The Babson system comprises a transport device having means for holding a plurality of vessels (e.g., loop 202) having a plurality of vessel holding members (e.g., 202a) via a motor (i.e., means for moving the vessel holding means). The transport device moves a plurality of vessels 840 along one or more continuous loops (e.g., 202, 213b, 213,215).

Babson teaches a transfer station in the wash station 214 and shown in detail in Figs. 8A-E. The transfer station includes a “means for moving 850” a reaction tube 840 vertically along the z-z axis direction and out of the vessel holding means 213b into vessel holding means 215, such as shown in FIG. 8A; see also col. 27, line 64- col. 30, line 55.

The system of Babson also includes a computer 12 (programmable controller), programmed to determine the individual path along the continuous loop for each of the vessels, wherein the determination of each path is based on resource requirement (i.e., duration of incubation) associated with each vessel ; see for example col. 7, line 40- col. 8, line 39 and col. 10, lines 17 et seq. That is, the computer control 12 of Babson allows the operator to pick the tests desired for each sample, and, if desired, to prioritize the sample if stat or unstable. The computer 12 instructs the instrument 10 to pick the right bead and right reagent and put them in a reaction tube with a particular sample for assay (i.e., another resource requirement). Based on the particular assay having a period of incubation, the computer determines how the reaction tubes will be processed along the individual paths. For instance, if the reaction tube needs to be advanced to wash and photometric analysis, the reaction tubes are shuttled out of the tube processor 213 and are picked up by a circular chain and moved to a high speed spin wash station 214. On the other hand, if additional incubation is desired for a sample, chain 213b is used to circle the reaction tube back to the beginning of the serpentine channel 213'. In addition, the reaction vessels can be returned to reaction pipetting station 204 by side chain 213b where more reagents is added (another resource

requirement), if necessary for the assay, before the steps of incubation and wash are repeated.

As to claim 31, the system of Babson includes two transfer stations (204; col. 5, lines 43-46 and 2nd transfer station disclosed at col. 17, lines 31-50) for removing a vessel from and replacing a vessel onto the transport device.

Regarding claim 32, the multi-path system of Babson also includes at least one delivery station 201 for adding a vessel to the transport device at a specified vessel holding member of the plurality of vessel holding members.

With respect to claim 33, the Babson system includes pipetting stations (207 and bead dispenser and carousel 203) for adding one or more reagents to a vessel positioned in a vessel holding member of the transport device.

As to claims 34-35, Babson also teaches wash stations 214 and 810 (fig. 8A) for washing test vessels positioned therein. Note that the Examiner considers the wash station combined with the transfer station (e.g., 213b) which transfers the tube from the wash station to either the side chain transport device 213' or luminometer chain 215a to a luminometer 216.

With respect to claims 36-37, Babson teaches a stationary agitating means (reaction tube shaker bars; not shown; see col. 7, lines 57+) positioned adjacent the transport device at a location where the vessels in the holding members contact the agitating member when the transport device 213 is moved.

Claims 30 and 38 include process limitations describing the movement of the transfer station. These limitations are considered merely an intended use which the

prior art would inherently be capable of doing. A recitation of function may not distinguish over Babson since an apparatus claim covers what a device is, not what it does. Nevertheless, regarding claim 38, the "means for moving" (i.e., motor) of Babson is able to move the one or more continuous loops (e.g., 202, 213b, 213) clockwise or counterclockwise around the loops (see for example arrows in Fig. 2B). Note the alternative claim language does not require the motor be able to do both.

Response to Arguments

16. Applicant's arguments filed March 03, 2008 have been fully considered but they are not persuasive. In response to the previous rejection of claims 1-4, 6-22, 25-26 under 35 U.S.C. 102(b) as being anticipated by Babson (US Patent no. 5,885,529), Applicant argues that Babson does not determine an individual path for each sample. Applicant alleges that the computer of Babson merely "allows the operator to pick the tests desired for each sample, and, if desired, to prioritized the sample if stat or unstable", otherwise the reference assay samples "methodically sequence around the carousel...".

The Examiner respectfully disagrees with Applicant's analysis of the Babson controller (i.e., computer 12). The entire instrument 10 of Babson is controlled by the computer controller 12. As discussed above, Babson teaches that the computer controller 12 allows the operator to pick the tests desired for each sample, and, if desired, to prioritize the sample if stat or unstable. The computer 12 can then instruct the instrument 10 to pick the right bead and right reagent and put them in a reaction

tube with a particular sample for assay (i.e., one type of resource requirement). Based on the particular assay having a particular duration of incubation (another type of resource requirement), the computer determines how the reaction tubes will be processed along the individual paths (213, 213', 213b, etc) before analysis. The Babson resource requirements correspond to the types of resource requirements cited in Applicant's invention, see page 10, lines 21-26 of Applicant's specification. These requirements include types of reagents added, duration of incubation, number wash cycles, etc.

Babson also teaches the controller determines the individual paths for each sample, based on the test desired for each sample. For instance, if the reaction tube needs to be advanced to wash and photometric analysis, the reaction tubes are shuttled out of the tube processor 213 and are picked up by a circular chain and moved to a high speed spin wash station 214 (first path). If additional incubation is desired for a sample, chain 213b is used to circle the reaction tube back to the beginning of the serpentine channel 213' (second path). In addition, the reaction vessels can be returned to reaction pipetting station 204 by side chain 213b where more reagents is added (resource requirement), if necessary for the assay, before the steps of incubation and wash are repeated (third path). See for example col. 7, line 40- col. 8, line 39 and col. 10, lines 17 et seq., of Babson.

Clearly, Babson does not subject the samples to the same path. Therefore, for the reasons delineated above, new claims 27-38 now stand rejected under 35 U.S.C. 102(b) as being anticipated by Babson (US Patent no. 5,885,529).

Conclusion

17. No claims are allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is (571)272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1797

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

pkw